

CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT: DOMESTIC AND IMPORTED CHEESE AND CHEESE PRODUCTS		IMPLEMENTATION DATE Upon Receipt
		COMPLETION DATE CONTINUING
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES	
INDUSTRY CODE: 12 USE APPROPRIATE PRODUCT CODES	1. <u>REPORT INSPECTIONS UNDER THE FOLLOWING PACS:</u> 03037 Inspections, Investigations, and Sample Collections 03037B Filth Analysis 03037D Microbiological and Phosphatase Analyses	

FIELD REPORTING REQUIREMENTS

NOTE: MICROBIOLOGICAL AND FILTH WORK FOR ALL CHEESE AND CHEESE PRODUCTS ARE COVERED UNDER THIS COMPLIANCE PROGRAM. MISUSE OF CHEMICALS BY THE FIRM AND COVERAGE OF ALL FOOD AND COLOR ADDITIVES IN CHEESE AND CHEESE PRODUCTS ARE COVERED UNDER THE DOMESTIC FOOD SAFETY (7303.803) AND IMPORTED FOODS - FOOD AND COLOR ADDITIVES (7309.006) COMPLIANCE PROGRAMS.

NUTRITION LABELING (NLEA), NUTRIENT CONTENT OPERATIONS, STANDARDS AND IDENTIFICATION FOR CHEESE AND CHEESE PRODUCTS ARE COVERED UNDER THE DOMESTIC AND IMPORT FOOD LABELING ENFORCEMENT (7321.005) COMPLIANCE PROGRAM.

REPORT ALL OPERATIONS EXPENDED FOR MONITORING THE CERTIFICATE AGREEMENT WITH FRANCE (AUDIT SAMPLES; [IMPORT ALERT 12-03](#), Detention Without Physical Examination of Imported Soft Cheese and Soft Ripened Cheese from France) AND CURRENT

DETENTIONS WITHOUT PHYSICAL EXAMINATION OF OTHER CHEESES FROM ALL COUNTRIES AGAINST THIS PROGRAM (PAC: 03037).

PART I - BACKGROUND

Cheese and cheese products may contain pathogenic microorganisms and thereby cause human illness. Some cheeses (primarily soft cheeses) have been linked to foodborne outbreaks and illnesses caused by *Salmonella*, *Listeria monocytogenes*, pathogenic *Escherichia coli* and enterotoxigenic *Staphylococcus aureus* contamination.

The presence of these pathogens is often times associated with poor GMPs, and/or an inadequate or total lack of a pasteurization process. For this reason, any cheese or cheese product that has been made from raw/ unpasteurized milk, without proper curing or use of a process that is an acceptable alternative to pasteurization as outlined in 21 CFR Part 133, is prohibited from introduction into interstate commerce as cited in 21 CFR Section 1240.61(a). The presence of alkaline phosphatase in levels exceeding the limits set forth in the standard identities for cheeses found in 21 CFR 133, is another indicator of inadequate pasteurization.

Due to continuing microbiological concerns associated with cheese and cheese products, this Compliance Program covers the sampling of domestic and imported cheese and cheese products for undesirable microorganisms as well as alkaline phosphatase and filth analysis.

PART II - IMPLEMENTATION

OBJECTIVE

- To conduct inspections of cheese manufacturers in the U.S. and cheese manufacturers in countries that export cheese to the United States.
- To collect and test samples of imported and domestic cheese for microbiological contamination, alkaline phosphatase and filth.
- To take appropriate action on imported lots and domestically produced cheese when violations are encountered and appropriate regulatory action(s) against the responsible firms.

Program Management Instructions

A. Import Alerts and Bulletins

Resources and operations expended for current Import Alerts/Bulletins to collect and test samples of cheese for microbiological contamination, alkaline phosphatase analysis and filth must be reported against this Compliance Program.

B. Examples of Five Cheese Categories

Below are five tables with examples of cheese varieties appropriate to each category. These tables are listed in order of the associated public health risk, with Soft Cheese varieties posing the greatest risk. Under this Compliance Program, priority should be given to Soft Cheese and Soft-ripened Cheese varieties, followed by Semi Soft Cheeses.

1. Examples of "Soft (fresh)" Cheese

Alemtejo	Cottage	Maigre	Queso Fresco
Alpin	Cream	Mignot	Provatura
Anari	Damen	Mont d'Or	Ricotta
Asadero	Farmers	Mozzarella	Scamorze
Asiago	Ferme	Neufchatel	Villiers
Bakers	Feta	Queso Blanco	Void
Banbury	Formagelle	Queso de Hoja	
Bondon	Gournay	Queso del Pais	
Cambridge	Livarot	Queso de Puna	

2. Examples of "Soft-ripened" Cheese

Barbery	Coulommiers	Monthery	Scholoss
Bel Paese	Crescenza	Old Heidelberg	Trouville

Bella Alpina	Gorgonzola	Reblochon	Vacherin
Bella Milano	Gouda	Robbiole	Vittoria
Brie	Kloster	Robbiolini	Vendome
Butter	Konigskrase	Rollot	
Camembert	Milano	Romadur	

3. Examples of “Semi-Soft” Cheese

Bellelay	Gammelost	Oka	Trappist
Blue	Havarti	Pont LEveque	
Brick	Herve	Port du Salut	
Camosun	Limburger	Provolone	
Chantelle	Maribo	Roquefort	
Edam	Molbo	Saint Paulin	
Fontina	Monterey	Stilton	
Fynbo	Muenster	Tilsit	

4. Examples of “Hard” Cheese

Abertam	Emiliano	Kefalotyri	Roll
Appenzeller	Emmentaler	Kjarsgaard	Romanello
Battelmatt	English Dairy	Laguiole	Romano
Bitto	Esrum	Lapland	Saloio
Bra	Fiore Sardo	Lorraine	Sassenage
Cantel	Fontina	Mecklenburg Skim	Swiss
Cheddar	Gex	Montasio	Tibet
Cheshire	Gislev	Mont Cenis	Tignard
Christalinna	Gloucester	Patagras	Toscanello
Colby	Gruyere	Piora	Uri
Coon	Karut	Queso de Prensa	Vize
Derby	Kasseri	Radener	

5. Examples of “Extra Hard” Cheeses

Bagos	Grana Trentino	Parmesan	Sbrinz
Bitto	Lodigiano	Parmesello	Schabzieger
Creusois	Lombardo	Peneteleu	Spalen
Grana	Mizen	Romano	Vasterbottenost
Grana Padano	Parmegiano Reggiano	Saanen	Walliskase

PART III - INSPECTIONAL

B. INSPECTIONAL

- Establishment inspections for domestic and imported cheese and cheese product manufacturers are to be conducted according to the following priority order:

1. Soft Cheese and Soft Ripened Cheese
2. Semi-Soft Cheese
3. Hard Cheese
4. Extra Hard Cheese
5. Cheese Products

Refer to ORA Workplan for the number of inspections to be conducted by Districts.

- Include inspection of the product(s) that will provide a complete description of a firm's condition and overall compliance status.
- Care should be taken during the inspection to fully identify possible routes of microbial contamination of the product and sources of filth. Also, because of the nature of bacterial contamination, in-line bacteriological sampling may be indicated. For further guidance on conducting inspections involving microbial contamination, and sampling instructions for products susceptible to pathogenic and non-pathogenic organisms, refer to the [IOM, Chapters 5 & 4 respectively](#). For further inspectional guidance on cheese plants, refer to the **Guide to Inspections of Dairy Product Manufacturers**, <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074974.htm>
- Observe and evaluate railcars, trucks and other vehicles used to off-load or load to insure food products are shipped under sanitary conditions. Refer to the Guidance for Industry Sanitary Transportation Of Food, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm208199.htm>
- Document if product time and temperature abuse is suspected.

B. SAMPLE COLLECTION

1. General Information

Refer to ORA Workplan and CFSAN Sample Collection Operations Planning Effort (SCOPE) for District sampling obligations. During scheduled inspections, collect samples when either of the following criteria has been met:

- the firm has a previous history of unmitigated microbiological contamination in the environment and/or in finished product (e.g., follow up to illness or

injury complaint, recalled/seized product, previous inspectional history, etc.), or

- sampling is conducted for cause (e.g., inspectional observations warrant collection of samples for microbiological analyses.)

Please Note- Unless filth analysis is indicated in the collection report, all samples collected under this compliance program will generally be analyzed for general micro and alkaline phosphatase only.

2. Sampling Priorities - Domestic and Import - When possible, samples are to be collected in the following priority order:

- a. Soft Cheese and Soft-ripened Cheese
- b. Semi-Soft Cheese
- c. Hard Cheese
- d. Extra Hard Cheese
- e. Cheese Products

NOTE: This excludes cheese subject to detention without physical examination in accordance with current Import Alerts. FDA typically does not sample products subject to DWPE.

3. Sample Size - Domestic and Import

For the purpose of this compliance program only, sample sizes to be collected are as follows: (Samples are to be collected in solid, shredded, grated, curds or extruded forms). Samples should be labeled according to IOM 4.5.2.

- a. Imports

- For solid cheese (wheels, loaves, or bricks) weighing from 4.54 kg (10 lbs.) or greater, collect a sample consisting of one (1) intact unit from the lot.
- For solid cheese (wheels, loaves, or bricks) ranging in weight from 2.27 kg (5 lbs.) to less than 4.54 kg (10 lbs.), collect a sample consisting of two (2) intact units from the same lot.
- For retail units (solid, shredded, grated, curds or extruded forms) ranging in weight from 454 g (1 lb.) to less than 2.27 kg (5 lbs.), collect a sample consisting of ten (10) intact units (subsamples) from the same lot.
- For retail units (solid, shredded, grated, curds or extruded forms) weighing less than 454 g (1 lb.), collect a sample containing of ten (10) subsamples with each subsample at least 454 g (1 lb.). For

example, if the product is only available in 227 g (8 oz.) units, collect twenty (20) intact units from the same lot. Therefore, two (2) units each will equal to one (1) subsample. Minimum total size for each sub sample should be 454g (1 lb.). Total sample size will be ten (10) pounds or slightly more.

NOTE: Larger retail packages should not be broken or cut to obtain a 454 g (1 lb.) subsample. Collect the intact retail unit as the subsample, even if it is larger than 454 g (1 lb.) Do not collect cheese portions that were cut from larger loaves, bricks or wheels and rewrapped at the retail level.

- SAMPLED IMPORTED PRODUCTS **MUST** BE HELD PENDING THE ANALYSIS RESULTS IN ACCORDANCE WITH 21 CFR 1.90.

b. Domestic

- For cheese wheels, loaves, or bricks weighing 4.54 kg (10 lbs.) or greater, collect a sample consisting of one (1) intact unit from the lot.
- For cheese wheels, loaves, or bricks ranging in weight from 2.27 kg (5 lbs.) to less than 4.54 kg (10 lbs.), collect a sample consisting of two (2) intact units from the same lot.
- For retail units (solid, shredded, grated, curds or extruded forms) ranging in weight from 454 g (1 lb.) to less than 2.27 kg (5 lbs.), collect a sample consisting of ten (10) intact units (subsamples) from the same lot.
- For retail units (solid, shredded, grated, curds or extruded forms) weighing less than 454 g (1 lb.), collect a sample containing of ten (10) subsamples with each subsample at least 454 g (1 lb.). For example, if the product is only available in 227 g (8 oz.) units, collect twenty (20) intact units from the same lot. Therefore, two (2) units each will equal to one (1) subsample. Minimum total size for each sub sample should be 454g (1 lb.). Total sample size will be ten (10) pounds or slightly more.

NOTE: Larger retail packages should not be broken or cut to obtain a 454 g (1 lb.) subsample. Collect the intact retail unit as the subsample, even if it is larger than 454 g (1 lb.). Do not collect cheese portions that were cut from larger loaves, bricks or wheels and rewrapped at the retail level.

- A separate 702(b) portion will not be necessary for samples collected to test for microbial analysis under this program per exemption 21 CFR 2.10(b)(3).
- Samples collected for other reasons may require a separate 702(b) portion.

4. Sample Shipment

- Ship samples to District's servicing microbiological laboratory.
- Refer to [IOM](#), Sections 4.5.3, for sample handling and 4.5.3.6 for specific information related to the handling of refrigerated samples.

5. Reporting

- Report collections of cheese and cheese products for microbiological contamination, alkaline phosphatase and filth ONLY against this Compliance Program. Refer to title page for appropriate PACs.
- NOTE: IF FILTH ANALYSIS IS DESIRED BY THE COLLECTING DISTRICT, INDICATE THAT REQUEST IN THE COLLECTION REPORT. IF FILTH ANALYSIS IS NOT SPECIFICALLY REQUESTED IN THE COLLECTION REPORT, THE LABORATORY WILL ANALYZE FOR GENERAL MICRO AND ALKALINE PHOSPHATASE ONLY.
- Record any suspected product abuse in the collection report, such as GMP issues, consumer illness, and/or lack of storage controls. This information will drive the laboratory to include additional pathogens in their microbiological analysis of the sample.
- The following Program Area Flags (PAFs) should be used to identify attributes to be analyzed for the sample collected:
 - o Microbiological and Alkaline Phosphatase- PAF: MIC
 - o Filth- PAF: FIL

PART IV - ANALYTICAL

A. MICROBIOLOGICAL AND PHOSPHATASE ANALYSIS

1. **Analyzing Laboratories:**

All field laboratories as specified in the current servicing laboratories chart under Appendix III of the ORA Field Workplan.

2. **Analyses to be performed:**

Each sample must be analyzed for the following seven (7) attributes:

- a. *Listeria monocytogenes*
- b. *Salmonella*
- c. *Escherichia coli*

NOTE: Non-toxigenic generic *E. coli* is not a human pathogen.

- d. Enterohemorrhagic *E. coli* (O157:H7) (EHEC) and Shiga toxin-producing *E. coli* (Non-O157:H7) (STEC)
- e. *Staphylococcus aureus*

NOTE: STAPHYLOCOCCAL ENTEROTOXIN TESTING WILL ONLY BE PERFORMED IF IT IS NOTED IN THE COLLECTION REPORT THAT PRODUCT ABUSE IS SUSPECTED, OR IF VIABLE STAPHYLOCOCCAL SPP. COLONIES, MPN RESULTS OR DIRECT PLATE COUNTS INDICATES A LEVEL AT OR ABOVE 1×10^4 /g.

- f. Alkaline Phosphatase
- g. Filth*

*NOTE: FILTH WILL BE PERFORMED ONLY UPON REQUEST

3. **Sample Preparation for Microbiological Analysis ([Table 1](#))**

For the purpose of this compliance program only, samples are to be prepared as follows:

- a. Import or Domestic Cheese – 2. 27 kg (5 lbs.) or greater

NOTE: IT IS VERY IMPORTANT TO REMOVE PORTIONS FOR MICROBIOLOGICAL ANALYSES FIRST BEFORE PERFORMING ALKALINE PHOSPHATASE ANALYSES.

SPECIAL PRECAUTIONS MUST BE TAKEN TO AVOID CONTAMINATING THE PORTIONS FOR MICROBIOLOGICAL ANALYSES AS WELL AS THE PORTION FOR PHOSPHATASE

ANALYSES WITH MICROBIAL PHOSPHATASE THAT MAY BE PRESENT ON THE SURFACE.

REMAINING PORTIONS ARE TO BE USED FOR FILTH ANALYSIS WHEN NECESSARY.

Since the product will be analyzed for multiple pathogens under this program, compositing and individual subsample analysis on the same sample will be necessary.

Listeria and *Salmonella*

Two (2) composites per sample will be analyzed. Obtain each composite aseptically,

- divide the cheese unit in half;
- take a plug of the cheese, which includes both surfaces from each half of the cheese unit;

For *Listeria* analysis, remove 125 g from each of the halves (250 g total), and blend or stomach them in 250 mL of BLEB without supplements (basal BLEB); 50 g of this composite blend (equivalent to 25g food plus 25 ml basal BLEB) is combined with 200 ml of basal BLEB. The composite is then inoculated as described by [BAM](#) chapter 10.

For *Salmonella* analysis, if sampling from a single wheel of cheese, remove 187.5 g from each of the halves in order to obtain a 375g composite.

To obtain the second composite for each analysis, repeat this process on the other individual unit of cheese.

NOTE: When compositing shredded, grated and extruded forms of cheese, remove the amount required for each composite from the packages aseptically in order to obtain the required composite amounts for *Listeria* and *Salmonella* analysis.

If a wheel of cheese weighs more than 10 lb., obtain one wheel per lot and prepare two composites from the wheel. If a wheel weighs between 5 and 10 lb., obtain two wheels and prepare one composite per wheel.

To obtain the second composite for analysis, repeat this process on the other packages.

E. coli, EHEC and STEC:

Aseptically, take 10 core subsamples from the wheel and analyze individually for EHEC O157:H7 and STEC. Analyze only 5 of those 10 core subsamples for generic *E. coli* (refer to [Part V](#), Regulatory/Administrative Follow-Up).

S. aureus:

Aseptically, take 10 core subsamples of 50 g and analyze for *S. aureus*.

b. Import or Domestic Cheese - retail units 454 g (1 lb.)

Since the product will be analyzed for multiple pathogens under this program, compositing and individual subsample analysis on the same sample will be necessary.

Listeria

Make two (2) composites from the ten (10) subsamples. To prepare a composite, remove 50 g from each of five (5) subsamples, and blend or stomach them in 250 mL of BLEB without supplements (basal BLEB); 50 g of this composite blend (equivalent to 25g food plus 25 ml basal BLEB) is combined with 200 ml of basal BLEB. The composite is then inoculated as described by [BAM](#) chapter 10.

Salmonella

Make two (2) composites from the ten (10) subsamples. Prepare each composite by removing 75 g from each of five (5) subsamples. Each composite will contain a total of 375 g.

NOTE: When compositing shredded, grated and extruded forms of cheese, remove the amount required for each composite from the packages aseptically in order to obtain the required composite amounts for *Listeria* and *Salmonella* analysis.

To obtain the second composite for analysis, repeat this process on the other packages.

E. coli, EHEC and STEC

Analyze 10 subsamples individually for EHEC O157:H7 and STEC. Analyze 5 of those subsamples for generic *E. coli*.

S. aureus

Analyze 10 subsamples, take 50 g each and test individually for *S. aureus*.

4. Sample Preparation for Phosphatase Analysis

a. Import or Domestic Cheese - subsamples 2.27 kg (5 lbs.) or greater

From the outer round edge of the cheese, remove the rind or the surface from the test sample with a clean knife. Ensure that the test sample is not contaminated with surface microflora during its preparation. The test portions to be analyzed are sampled by taking a portion of 1 cm thick, taken at 0.5 cm below the rind of the round side.

NOTE: SPECIAL PRECAUTIONS MUST BE TAKEN TO AVOID CONTAMINATING SAMPLE WITH MICROBIAL PHOSPHATASES THAT MAY BE PRESENT ON THE SURFACE OF THE CHEESE.

For samples of shredded, grated or extruded forms of cheese, remove 15 g from the unit aseptically for analysis.

b. Import or Domestic Cheese - retail units 454 g (1 lb.)

Randomly select two (2) subsamples.

From the outer round edge of the cheese, remove the rind or the surface from the test sample with a clean knife. Ensure that the test sample is not contaminated with surface microflora during its preparation. The test portions to be analyzed are sampled by taking a portion of 1 cm thick, taken at 0.5 cm below the rind of the round side

NOTE: SPECIAL PRECAUTIONS MUST BE TAKEN TO AVOID CONTAMINATING SAMPLE WITH MICROBIAL PHOSPHATASES THAT MAY BE PRESENT ON THE SURFACE OF THE CHEESE.

Table 1: Sample Preparation

Cheese weight	<i>Salmonella</i>	<i>Listeria</i>	<i>E. coli</i> , and EHEC/STEC	<i>S. aureus</i>
>10 lb	• obtain one wheel per lot • prepare two composites from the wheel • divide the wheel in half • take a plug of 187.5g cheese, which includes both surfaces from each of halves in order to obtain a 375 g composite • repeat this process to obtain the second composite	• obtain one wheel per lot • prepare two composites from the wheel • divide the wheel in half • take 5 plugs of 50g cheese each, blend in 250 mL of BLEB without selective agents in order to obtain a composite • repeat this process to obtain the second composite	• obtain one wheel per lot • take 10 plugs of 25 g each and test individually for EHEC/STEC • take 5 plugs of 50 g each and test for generic <i>E. coli</i>.	• obtain one wheel per lot • take 10 plugs of 50 g each and test individually for <i>S. aureus</i>
5 lb to <10 lb	• obtain two wheels per lot • prepare one composite per wheel • take 2 plugs of 187.5g cheese, which includes both surfaces from the wheel in order to obtain a 375 g composite • repeat this process on the other wheel to obtain the second composite	• obtain two wheels per lot • prepare one composite per wheel • take 5 plugs of 50g cheese each, blend in 250 mL of BLEB without selective agents in order to obtain a composite • repeat this process to obtain the second composite	• obtain two wheels per lot • take 5 plugs of 25 g from each wheel and test individually for EHEC/STEC • take 5 plugs of 50 g each (2/3 split from 2 wheels) and test for generic <i>E. coli</i>.	• obtain two wheels per lot • take 5 plugs of 50 g from each wheel and test individually for <i>S. aureus</i>

Cheese weight	<i>Salmonella</i>	<i>Listeria</i>	<i>E. coli</i> , and EHEC/STEC	<i>S. aureus</i>
< 5 1b	• make 2 composites from the 10 subsamples • Prepare each composite by removing 75 g from each of 5 subsamples in order to obtain a 375 g composite	• make 2 composites from the 10 subsamples • From each of the 5 subsample, take 50g cheese, blend in 250 mL of BLEB without selective agents in order to obtain a composite • repeat this process to obtain the second composite	• obtain 10 subsamples, take 25 g and test individually for EHEC/STEC • take 50 g from 5 subsamples and test for generic <i>E. coli</i>.	• obtain 10 subsamples, take 50 g and test individually for <i>S. aureus</i>

Methodology

a. *Listeria monocytogenes*

Examine (2) composites.

Safety Precautions: Media preparation for *L. monocytogenes* directs the use of cycloheximide which is an **extremely toxic** chemical. Likewise, the *L. monocytogenes* method requires the use of acriflavin HCl which is a powerful mutagen. Use caution: Avoid skin contact or aerosol formation and inhalation.

Since the *L. monocytogenes* method gives the option of using a - naphthol, **DO NOT** use a - Naphthylamine. All analysts should take **extreme safety precautions** when handling this chemical; i.e., weigh in a containment hood free of drafts; wear gloves and face mask. Those laboratories with pesticide capabilities should take additional precautions against possible contamination as cycloheximide is a fungicide.

Isolation and identification: Refer to [BAM](#) online. Rapids test kit methods validated as AOAC OMA methods can be used. If *L. monocytogenes* is detected in the sample, enumeration of the level of contamination in the food is required and representative isolated cultures should be sent to DEN for phage typing.

For phage typing, send a copy of the collection report and analyst worksheet for each sample. Place accompanying records inside the

shipping container, but not in the culture container. Ship according to Federal Standards for etiological agents to:

Sample Custodian
Food and Drug Administration
6th Avenue & Kipling Street
Denver Federal Center
Building 20
Denver, Colorado 80225-0087

b. *Salmonella*

Examine (2) composites.

Isolation and identification: Refer to [BAM](#) online, chapter 5 (May 2014 Version).

Either the VIDAS *Salmonella* SLM (AOAC OMA method 2004.03 or 996.08)
or
VIDAS *Salmonella* SLM Easy (AOAC 2011.03) may be used in this assignment.

Add 187.5 g cheese to a sterile blender jar containing 1687.5 mL lactose broth and blend for 2 min at 10,000 – 12,000 rpm. Repeat with a second 187.5 g cheese portion. Combine the contents of the 2 blender jars into a single 4 L flask (or any other appropriate container). The combined contents of the 2 blender jars shall constitute a single 375 g composite. Repeat procedure with two 187.5 g cheese portions to form the second 375 g cheese composite.

Allow flasks to stand for 60 ± 5 min at room temperature. Mix well and determine the pH with test paper. Adjust pH, if necessary, to 6.8 ± 0.2 with sterile 1 N NaOH or 1N HCl.

Test according to VIDAS SLM and Easy SLM assays

- For the VIDAS *Salmonella* SLM and Easy SLM assays incubate flasks without shaking for 18-24 h at 34-36° C.
- For the VIDAS SLM Assay for *Salmonella* transfer 0.1 ml lactose broth to 10 ml RV medium and transfer another 1.0 ml of pre-enrichment broth to 10 ml TT broth and incubate in a circulating, thermostatically controlled water bath for 18-24 h at 41-42°C. Subculture 1.0 ml aliquots from the incubated TT and

RV broths to separate tubes containing 10 ml portions of M-broth (post enrichment) and incubate at 41-42°C for 6-8 h. Continue as described in the kits instructions (AOAC Official Method of Analysis 2004.03 or 996.08).

- For the VIDAS® Easy Method (OMA First Action Method 2011.03), transfer 0.1 ml preenrichment broth to 10 ml SX2 broth and incubate in a circulating, thermostatically controlled water bath for 16-22 h at 42±1°C. Continue as described in the kits instruction.
- Presumptive positive samples must be confirmed culturally by streaking selective enrichments to selective agars as described in the BAM, May 2014 Version, Chapter 5, section D-3 and section D-4 (<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm>). Continue as described in the BAM.

Speciation

Submit cultures on brain heart infusion (BHI) agar slants and provide hardcopy information as directed in BAM, Chapter 5, section E.11. (<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm>) and send to:

Isolates from NRL, WEAC, SRL and ARL will be serotyped in ARL:

Arkansas Regional Laboratory
3900 NCTR Road Building 26
Jefferson, AR 72079
Attention: Gwendolyn Anderson
Phone: 870-543-4621

Isolates from SAN, PRL-NW, PRL-SW and DEN will be serotyped in DEN:

Denver District Laboratory
6th Avenue & Kipling Street
DFC Building 20
Denver, CO 80225-0087
Attention: Shauna Madson
Phone: 303-236-9631

- c. *E.coli* (non-toxigenic generic *E.coli*)
- **Examine only five (5) subsamples individually. Do Not conduct testing on each individual 10 (ten) subsamples allocated for *Listeria monocytogenes* and *Salmonella* or pathogenic *E.coli* (EHEC and STEC)**
 - **Isolation, identification, and enumeration:** Refer to [BAM](#), Online, Chapter 4, Section I.
 - Alternatively, the use of a fluorogenic substrate method for enumerating for *E. coli* in cheese has also been cleared by ORS (DFS) per Notification No: 2009-10-29. Microbiology Operations – Cheese Program – Use of ColiComplete Procedure and Confirmation Steps for *E. coli* Identification.
 - The following also pertains to cheese analysis. Notification No: 2009-11-13. Microbiology Operations – Cheese Program – *E. coli*, MPN Analysis.
- d. Enterohemorrhagic *E.coli* (O157: H7) and Shiga toxin-producing *E. coli* (Non-O157:H7) STEC
- Examine each of the 10 subsamples individually.
 - "Screening Methods for Enterohemorrhagic *E. coli* (EHEC) and STEC", refer to [BAM](#), Online, Chapter 4A, Sec. K.
- e. *Staphylococcus aureus*
- Examine each of the 10 subsample individually.
 - **Methods for identification, enumeration, coagulase, ancillary tests, and Most Probable Number** -- Bacteriological Analytical Manual, Online: Chapter 12, *Staphylococcus aureus* (<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071429.htm>) and Appendix 2, Most Probable Number from Serial Dilutions, (<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm109656.htm>).
 - Enterotoxin testing is recommended when: direct plate counts indicate a level of greater than or equal to 10^4 cfu/g; MPN results of greater than or equal to 10^4 MPN/g; or if product time and temperature abuse is suspected.

Staphylococcal Enterotoxin Determination

- **Methods for staphylococcal enterotoxin testing** -- Bacteriological Analytical Manual, Online: Chapter 13A, Staphylococcal enterotoxins (<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm073674.htm>). There is zero tolerance for staphylococcal enterotoxin presence in foods. Detection of any level of staphylococcal enterotoxin is justification that the food is unfit for consumption.

NOTE: Some species of *Staphylococcus* produce an enterotoxin that is extremely heat stable and not destroyed during food processing procedures or pasteurization temperatures. Therefore, it's possible to have staphylococcal enterotoxin presence without viable *Staphylococcus aureus*. If the product is suspected to have caused staphylococcal food poisoning and undergone retort procedures, see references 11 and 12 in the BAM for alternative detection methods for staphylococcal enterotoxin.

f. Alkaline Phosphatase

NOTE: Any cheese sample that has been made from raw/ unpasteurized milk, without proper curing or use of a process that is an acceptable alternative to pasteurization as outlined in the applicable regulation in 21 CFR Part 133, is prohibited from introduction into interstate commerce as cited in 21 CFR 1240.61(a).

Products to be Analyzed

- Soft/semi-soft/soft-ripened cheese samples **MUST** be analyzed for alkaline phosphatase and for all the other attributes specified under A. 2. "Analyses to be performed".
- Soft cheeses containing **herbs** **MUST** be analyzed for alkaline phosphatase and for all the other attributes specified under A. 2. "Analyses to be performed".
- Naturally aged (cured) cheese samples should **NOT** be analyzed for alkaline phosphatase, but **MUST** be analyzed for all the other attributes specified under A. 2. "Analyses to be performed".

NOTE: A naturally aged cheese is one made from unpasteurized milk which has been cured at a temperature of not less than 35 degrees F for not less than 60 days.

- Other cheeses that are labeled as either pasteurized or made from dairy ingredients that have all been pasteurized **MUST** be analyzed for alkaline phosphatase and for all the other attributes specified under A. 2. "Analyses to be performed".

Screen Analysis

To determine the amount of alkaline phosphatase in a cheese sample, refer to [BAM](#), online Chapter 27, "Screening Method for Phosphatase (Residual) in Cheese".

NOTE: Do **NOT** perform this screening method on any ****soft**** cheeses containing **herbs**. Instead perform the method, referenced under 3) Check Analysis below, directly on these cheeses to determine the phenol equivalent value.

Refer to Table 1 of [BAM, Chapter 27](#) for the maximum phenol equivalent values allowed in different types of cheese and the 21 CFR Part 133 reference.

A sample is violative for alkaline phosphatase:

- if the cheese is listed in [ATTACHMENT B](#), and the phenol equivalent value per gram is greater than the value listed for the cheese in ATTACHMENT B; or,
- if the cheese is NOT listed in [ATTACHMENT B](#), and the phenol equivalent value per gram is greater than 12 mg.

Check Analysis

Check analyses **MUST** be performed on **ALL** violative samples.

Method: [AOAC](#), 18th Ed., 33.7.27 AOAC Official Method 946.03, Phosphatase (Residual) in Cheese.

NOTE: This method is equivalent to AOAC Method 16. 275-16. 277 (13th Ed., 1980), cited in 21 CFR 133.5(c).

If a district laboratory chooses to use the AOAC method for the screening method then the check analysis is for a different analyst to run the AOAC method.

B. FILTH ANALYSIS

If filth analysis is not specifically requested in the collection report, the laboratory should not perform filth analysis.

1. Analyzing Laboratories: All field laboratories as specified in the current servicing laboratories chart under Appendix III of the ORA field workplan.
2. Sample Preparation Instructions for Filth Analysis
 - a. Import or Domestic Cheese - subsamples 2. 27 kg (5 lbs.) or greater
Remove six (6) - 227 g (8 oz.) subsamples from the unit of cheese. For samples of shredded, grated or extruded forms of cheese, remove the same amount.

NOTE: Each subsample should be examined individually and not composited.

- b. Import or Domestic Cheese - consumer size units, 227 g (8 oz.)

Randomly select six (6) subsamples from the remaining portions of the ten (10) subsamples used for micro and alkaline phosphatase analysis. Remove 227 g (8 oz.) from each of the six (6) subsamples for analysis. For samples of shredded, grated or extruded forms of cheese, remove the same amount.

NOTE: Each subsample should be examined individually and not composited.

3. Analytical Guidance

Filth, Mold and Foreign Objects: Microscopic and Macroscopic

Methodology: AOAC, 16th Ed., Chapter 16, Extraneous Materials:

Isolation, AOAC 18th Ed. Official Method 994. 05 (see 16.3. 04), Light Filth in Cheeses page 12.

If not applicable, then use:

AOAC, 18 Ed., Chapter 16, Extraneous Materials: Isolation, AOAC Official Method 960.49 (see 16. 3. 03), Filth in Dairy Products, pages 11-12.

C. ANALYTICAL REPORTING

Report all microbiological, alkaline phosphatase and filth analyses against this Compliance Program. Refer to the title page for appropriate PACs.

DO NOT REPORT ANALYSES FOR CHEMICAL MISUSE, FOOD/COLOR ADDITIVES, OR NUTRITION LABELING (NLEA)/NUTRIENT CONTENT AGAINST THIS PAC.

1. Microbiological and alkaline Phosphatase

- ORA/ORS will notify CFSAN and ORA/OFFO/FFPOB of the results of the speciation at ORA HQ FOOD FEED PROGRAM REPORTING.
- Laboratories will enter data into FACTS.
- LMS data entry for Salmonella - Use Form Code "MIC" and Flag Code "MIC"
- The analyzing laboratory should inform the collecting District when the lab cannot rule out (CRO) a pathogen finding and as soon as there is confirmation of a pathogen finding or non-finding in a sample collected under this compliance program.

2. Filth

- Record all filth findings on [Attachment A](#). Also, when completing Attachment A, be sure to indicate the method used on the form. This form should be shared with the home district and ORA/ OFFO/FFPOB @ ORA HQ FOOD FEED PROGRAM REPORTING.

3. Sharing information with State Counterpart:

The Districts, ORA/Office of Partnerships (ORA/OP), and ORA/ORS will coordinate State involvement including sharing of FDA analytical results, which may be performed under contract, cooperative agreement, partnership agreement, or other collaborative efforts.

Table 2: Sample Analysis

Sample Analysis for Salmonella	BAM online, Chapter 5 (May 2014 Version): http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm .
Sample Preparation	• Add 187.5 g cheese to a sterile blender jar containing 1687.5 mL lactose broth and blend for 2 min at 10,000 – 12,000 rpm, or 187.5g of cheese should be blended with a sufficient volume of lactose broth to adequately blend the cheese and then bringing the total volume up to 1875mls. • Repeat with a second 187.5 g cheese portion. • Combine the contents of the 2 blender jars into a single 4 L flask (or any other appropriate container). The combined contents of the 2 blender jars shall constitute a single 375 g composite. • Repeat procedure with two 187.5 g cheese portions to form the second 375 g cheese composite.

	Allow flasks to stand for 60 ± 5 min at room temperature. Mix well and determine the pH with test paper. Adjust pH, if necessary, to 6.8 ± 0.2 with sterile 1 N NaOH or 1N HCl.
Preenrichment	Incubate flasks without shaking for 22-26 h at $35 \pm 2^\circ$ C. Or if VIDAS <i>Salmonella</i> SLM and Easy SLM assays will be used, incubate flasks as instructed by the kit manufacturer.
Selective enrichment	Follow the BAM online, Chapter 5 (May 2014 Version): http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm. Or if VIDAS <i>Salmonella</i> SLM and Easy SLM assays will be used, selectively enrich as instructed by the kit manufacturer.
Isolation and Identification	Follow the BAM online, Chapter 5 (May 2014 Version): http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm.
Culture submission	Follow the BAM online, Chapter 5 (May 2014 Version): http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm.
Sample Analysis for <i>Listeria</i>	BAM online (Chapter 10) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400.htm
Sample Preparation	From the prepared composite mix, 50 g is added to 200 mL of BLEB without selective agents
	Incubate for 4 h at 30°C. Add the selective agents and continue incubating for a total time of 48 h at 30° C.
	VIDAS <i>Listeria</i> AOAC 999.06 or 2004.06
	Follow BAM online (Chapter 10) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400.htm
	Follow BAM online (Chapter 10) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400.htm

Sample Analysis for <i>E.coli</i> and EHEC	<i>E. coli</i> – use the MPN method described in Chapter 4. Online BAM http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm064948.htm The fluorogenic method using ColiComplete is also permitted for cheese testing as per DFS Notification No: 2009-10-29. EHEC/STEC – Use method described in Chapter 4A. Online BAM http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070080.htm
Sample Preparation	<i>E. coli</i> – Blend 50 g sample in 450 ml Butterfield’s phosphate buffered water. Do 10 fold serial dilutions and inoculate LST tubes. Follow

	MPN procedure as described in Chapt. 4, Sec. I.C. of the BAM procedure. EHEC/STEC – Blend or stomach 25 g of sample in 225 ml mBPWp.
Preenrichment/ selective enrichment	EHEC/STEC – follow procedure described in Chap. 4A Sec. N.2.
Screening enrichment sample	EHEC/STEC – use the rt-PCR method described in Chap. 4A, Sec. K. of the BAM procedure.
Isolation and identification	EHEC/STEC – used method described in BAM Chap. 4A, Sec. P for O157:H7 and Sec. R. for STEC.

Sample Analysis for <i>S. aureus</i>	<i>S. aureus</i> –Use the MPN method for routine surveillance of products in which small numbers of <i>S. aureus</i> are expected and direct plate count method when more than 100 <i>S. aureus</i> cells/g may be expected, as described in the Chapter 12, <i>Staphylococcus aureus</i> . Online BAM. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071429.htm and Appendix 2, Most Probable Number from Serial Dilutions. Online BAM. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm109656.htm
Sample Preparation	<i>S. aureus</i> – Blend 50 g sample in 450 ml Butterfield’s phosphate buffered water. Follow MPN procedure as described in Chapter 12, <i>Staphylococcus aureus</i>. Online BAM. Chapter 12, <i>Staphylococcus aureus</i> . Online BAM.
Preenrichment/ selective enrichment	<i>S. aureus</i> – Inoculate 3 tubes of TSB containing 10% NaCl and 1% sodium pyruvate with 1 ml portions of decimal dilutions of each sample. Follow procedure described in Chapter 12, <i>Staphylococcus aureus</i>. Online BAM.
Screening enrichment sample	<i>S. aureus</i> – follow procedure described in Chapter 12, <i>Staphylococcus aureus</i>. Online BAM.
Isolation and identification	<i>S. aureus</i> – use the identification methods described in Chapter 12, <i>Staphylococcus aureus</i>. Online BAM.
Additional testing	Enterotoxin testing is recommended when: direct plate counts indicate a level of greater than or equal to 10⁴ CFU/g; MPN results of greater than or equal to 10⁴ MPN/g; or if product time and temperature abuse is suspected.
Methods for staphylococcal enterotoxin testing	Staphylococcal Enterotoxin testing - use the detection methods as described in Chapter 13A, <i>Staphylococcal enterotoxins</i>. Online BAM. (http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm073674.htm). There is zero tolerance for staphylococcal enterotoxin presence in foods. Detection of any level of staphylococcal enterotoxin is justification that the food is unfit for consumption

PART V - REGULATORY/ADMINISTRATIVE FOLLOW-UP

Districts should use the following table to aid in determining appropriate regulatory response to microbiological contamination, filth or phosphatase results. The overarching compliance goal is to remove adulterated product from the market, and prevent future entry of adulterated product into the market.

Regulatory activities that should be considered in both domestic and import cases include:

- The recommendation of a follow up comprehensive GMP inspection to determine potential source(s) of contamination;
- When pathogens are detected, further sampling efforts should consider testing of raw materials (incoming raw milk if pathogenic *E. coli* was detected in cheese), finished product cheese and/or swabbing of the processing environment (of domestic manufacturers) to verify adequacy of sanitation;
- A review of PFGE and whole genome sequencing data to investigate related food, environment and clinical isolates;
- Working with the firm to obtain prompt voluntary corrective actions to address violative findings; and
- A determination as to whether controls and checks are in place to provide assurance of product safety.

The following Table lists the sample results and possible regulatory responses with FD&C Charges:

Sample Result	FD&C Act Charge	Possible Response¹
<i>Salmonella</i> <i>Listeria monocytogenes</i> Enterohemorrhagic <i>E. coli</i> (O157:H7) and Shiga toxin-producing <i>E. coli</i> (Non-O157:H7) ²	DOMESTIC 402(a)(1)	• Voluntary recall • Administrative Detention • Seizure • Injunction • Mandatory recall • Suspension of Registration • Environmental sampling at manufacturing site (if <i>Salmonella</i> or <i>L. monocytogenes</i> is detected) • Sampling of raw milk (if pathogenic <i>E. coli</i> is detected)

¹ See CPG Sec. 527.300, Dairy Products- Microbial Contamination and Alkaline Phosphatase Activity (**currently being updated**).
<http://www.fda.gov/downloads/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm238480.pdf>

² Samples that are only positive for *stx1* and/or *stx2* are indicative that non-O157 STEC may be present. There are ~ 300 serotypes of STEC and not all appear to cause severe illness in humans, therefore, these isolates require further testing. Follow the procedure described in BAM Chap. 4A, Sec. R. for isolation of non-O157 STEC. Send the STEC isolate to Peter Feng, CFSAN, for additional testing to determine if is a STEC strain of health concern.

Sample Result	FD&C Act Charge	Possible Response ¹
Staphylococcal enterotoxin charge		
Bacillus cereus enterotoxin	IMPORT 402(a)(1)/ 801(a)(3)	• Detention/Refusal • Addition of firm/product to Import Alert 12-10 • Consider increased import sampling • Consider inspection of foreign firm (Direct reference for import actions based on <i>Salmonella</i> and <i>Listeria monocytogenes</i>) <i>Staphylococcus</i> enterotoxin, or <i>Bacillus cereus</i> enterotoxin) http://inside.fda.gov:9003/PolicyProcedures/Compliance/DirectReference/default.htm
Non-toxigenic (generic) <i>E. coli</i> ³ - Levels exceeding 10 MPN/g but less than 100 MPN/g in three or more subsamples of the five examined; or levels at or above 100 MPN/g in one or more subsamples of the five examined	DOMESTIC 402(a)(4)	• Warning Letter • Regulatory Meeting • Seizure of adulterated lot
<i>S. aureus</i> - Greater than or equal to 10 ⁴ colony forming units per gram (cfu/g) <i>B. cereus</i> - Greater than or equal to 10 ⁴ colony forming units per gram (cfu/g)	IMPORT 402(a)(4)/ 801(a)(3)	• Detention/Refusal • Addition of firm/product to Import Alert 12-10 • Consider increased import sampling • Consider inspection of foreign firm
Alkaline Phosphatase	DOMESTIC 402(a)(4)	• Determine if there is evidence that bovine milk is inadequately pasteurized or unpasteurized • Warning Letter
	IMPORT 402(a)(4)/ 801(a)(3)	• Consider Detention/refusal • Consider inspection of foreign firm
Filth	DOMESTIC 402(a)(3)	• Warning Letter • Seizure of adulterated lot

³ Discuss any excessive generic *E. coli* findings with the Center.

Sample Result	FD&C Act Charge	Possible Response ¹
	IMPORT 402(a)(3)/ 801(a)(3)	• Detention/refusal • Consider inspection of foreign firm

Consider referral to the State when:

There is no interstate, AND

There is no evidence of widespread contamination.

Follow up with the state should include discussion of activities the State plans to initiate on the remaining product at the retail level and/or processing plant (if applicable).

Consider a voluntary recall when:

Implicated product is on the market.

Consider a mandatory recall when:

Implicated product is on the market, AND

The party in control of the product refuses to recall voluntarily, AND

The party in control of the product is a facility as defined in 21 CFR 1.227(2)(i), AND

There is clear evidence of serious adverse health consequences or death to humans or animals.

Consider administrative detention when:

A seizure is contemplated, AND

The Agency needs to quickly gain control of the food while the seizure case is built.

Consider a seizure when:

The product is in domestic commerce, AND

The amount of product meets the seizure monetary threshold in the RPM and,

The firm refuses to voluntarily destroy or recondition the product.

Consider detention when:

The implicated product is in import status.

Consider DWPE when:

The conditions of [Import Alert 12-10](#), Detention Without Physical Examination of Cheese Due to Microbiological Contamination have been met.

Domestic products:

- If an investigator suspects that a carrier, through the conditions on its transport vehicles, may have been responsible for the contamination of food, follow the guidance provided in [CPG 545.300](#), Foods, Rail Car Sanitation – Adulteration, with regard to action against the carrier (.
- When finished product samples are positive for presence of *Listeria* or *Salmonella*, districts may consider direct reference seizure of the cheese and cheese products as authorized (see [CPG Sec. 527.300](#), Dairy Products- Microbial Contamination and Alkaline Phosphatase Activity.

- If no INTERSTATE documentation can be associated with violative intrastate cheese samples, contact State authorities to coordinate appropriate follow-up activities. Provide assistance to the State for sanctioning their follow-up activity, if requested.

Import Products:

- Recommendations for detention without physical examination of imported products should be referred to the Division of Import Operations, Import Operations and Maintenance Branch through CMS.
- Districts may consider detention of cheese and cheese products when samples are positive for presence of human pathogens and enterotoxins as authorized (see [CPG Sec. 527.300](#), Dairy Products- Microbial Contamination and Alkaline Phosphatase Activity).
- For imported products that are in domestic or domestic/import status, notify the CFSAN/ DE regulatory contact listed in [PART VI](#), under section C. PROGRAM CONTACTS, for further guidance if the levels for *E. coli*, Enterohemorrhagic *E. coli*, STEC or *Staphylococcus aureus* are found at or above the levels mentioned in the above Table.
- For imported products, refer to the appropriate Compliance Policy Guides and Import Alerts for further guidance. In the absence of a CPG or Import Alert, notify the CFSAN/DE regulatory contact listed in [PART VI](#), under section C. PROGRAM CONTACTS, for further guidance if the levels stated above are found.
- Recommendations for detention must be accompanied by all analytical worksheets (original and check, when required) and other appropriate documentation (entry paperwork, collection report, labeling, etc.).
- Recommendations for detention without physical examination of imported products should be referred to the Division of Import Operations, Import Operations and Maintenance Branch through CMS.

Alkaline phosphatase samples for both domestic and imported products:

Districts should submit recommendations for regulatory action based on phosphatase findings to CFSAN using the following criteria:

- For standardized cheeses with phenol equivalent value cited in [21 CFR Part 133](#).
 - a. A cheese sample with a phenol equivalent value per gram greater than the value listed in [Attachment B](#). The table lists the type of cheese, the maximum phenol equivalent value allowed per gram of cheese, and the appropriate 21 CFR reference.

- For standardized cheeses without a phenol equivalent value cited in [21 CFR Part 133](#) and non-standardized cheeses:
 - a. a cheese sample made from PASTEURIZED milk with a phenol equivalent value per gram greater than 12 mg, or
 - b. a cheese sample made from UNPASTEURIZED milk and cured (aged) properly with a phenol equivalent value per gram greater than 12 mg, or
 - c. ANY cheese sample made from either RAW or UNPASTEURIZED milk without proper curing or use of a process that is an acceptable alternative to pasteurization as outlined in 21 CFR Part 133. 21 CFR 1240.61(a) prohibits such cheeses from introduction into interstate commerce.

NOTE: BEFORE RECOMMENDING REGULATORY ACTION, CHECK ANALYSES MUST BE PERFORMED ON ALL VIOLATIVE SAMPLES USING THE AOAC 16TH EDITION METHOD 943. 03 (33. 7.27), APHOSPHATASE (RESIDUAL) IN CHEESE (FINAL ACTION). THIS METHOD IS EQUIVALENT TO THE AOAC 13TH EDITION METHOD, APHENOL EQUIVALENT VALUE, SECTIONS 16. 275-16. 277, AS CITED IN [21 CFR PART 133, SECTION 133. 5\(c\)](#).

PART VI - REFERENCES, ATTACHMENTS AND PROGRAM CONTACTS

A. ATTACHMENTS

[Attachment A](#) -Analytical Reporting Form - Filth Analyses

[Attachment B](#) -List of Standardized Cheeses with Phenol Levels from 21 CFR Part 133

B. REFERENCES

For inspectional guidance and sampling instructions for products susceptible to pathogenic and non-pathogenic organisms, refer to [IOM](#), Chapter 4 and 5.

Guide to Inspections of Dairy Product Manufacturers,
<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074974.htm>

Bacteriological Analytical Manual (BAM)
<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>

Refer to [BAM](#), Chapter 27, Screening Method for Phosphatase (Residual) in Cheese, Section C, [Sampling of Cheeses](#), for sample preparation.

Refer to [BAM](#) online. Rapids test kit methods validated as AOAC OMA methods can be used.

Refer to [BAM](#) online, Chapter 5 (May 2014 Version) isolation and identification of *Salmonella*.

C. PROGRAM CONTACTS

Program Contact:

Kaniz Shireen, CFSAN/OC/Division of Field Programs and Guidance/ Program and Assignment Monitoring Branch, HFS-615, (240) 402-2775

Regulatory Contact:

Domestic and Domestic/Imports - Priya Rathnam, CFSAN/OC/Division of Enforcement/Food Adulteration Assessment Branch, HFS-607, (240) 402-2078

CFSAN Scientific Contact:

Donald Zink, CFSAN/Office of Food Safety, HFS-006, (240) 402-1693

CFSAN Program Office Contact:

Monica Metz, CFSAN/Office of Food Safety/ Division of Dairy, Egg & Meat Products/Milk and Milk Products Branch, HFS-316, (240) 402-2041

ORA/ORS Scientific Contact:

Peggy Carter, ORA/ORS, HFS-141, (301) 796-6239.

ORA/DIO Import Operations Contact:

Chauncey Stephens, OGROP/ORA/OO/OEIO/DIO, HFR-SE670, (404) 575-1521, X1521

ORA/OFFO Contact:

Martha Sullivan-Myrick, ORA/OO/OFFO/DFFPOI/FFPOB, HFR-CE7555 (616) 304-6283.

D. SPECIFIC METHOD CONTACTS

- *E. coli*, Enterohemorrhagic *E. coli* (EHEC) and STEC - Peter Feng, CFSAN/Division of Microbiology/Microbiology Methods Development Branch, HFS-711, (240) 402-1650
- *Salmonella* - Thomas Hammack., CFSAN/Division of Microbiology/Microbial Methods Development Branch, HFS-711, (240) 402-2010
- *Listeria* - Yi Chen, CFSAN/Division of Microbiology/Microbial Methods Development Branch, HFS-710, (240) 402-2783
- Alkaline Phosphatase/ Filth - George C. Ziobro, CFSAN/OFS/Division of Dairy, Egg & Meat Products/Milk and Milk Products Branch , HFS-316, (240) 402-1965
- *Staphylococcus aureus* – Reginald Bennett, CFSAN/Division of Microbiology, HFS-711, (240) 402-2009 or Jennifer Hait (240) 402-2569

PART VII - CENTER RESPONSIBILITY

The Director, Division of Dairy, Egg and Meat products (DDEMP), HFS-315 will evaluate the effectiveness of the program and provide further guidance to the Director, Office of Compliance as appropriate. Working in conjunction with the Program Office, the Program Evaluation Branch (PEB) of the Division of Field Programs and Guidance (DFPG) will prepare a yearly summary report for this compliance program. The summary will outline the Program Office's current objectives, highlight their accomplishment data for the year, and list recommendations for the upcoming year. The report will be made available on the Inside.FDA intranet site under the Programs and Initiatives page:

(<http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm015369.htm>).

ATTACHMENT A

CHEESE FILTH REPORTING FORM						
FY: _____ SAMPLE NUMBER: _____ METHOD NO. SUBSAMPLE WT. _____						
COLLECTING DISTRICT: _____ ANALYZING LABORATORY: _____						
COUNTRY OF ORIGIN: _____ PRODUCT NAME: ** _____						
MANUFACTURER/DISTRIBUTOR: _____						
FiltH Findings	Subsample Number					
	1	2	3	4	5	6
1. W/E Stored Product Insects*						
2. W/E FiltH Insects*						
3. W/E Other Insects*						
4. Insect Fragments – Stored Product*						
5. Insect Fragments – FiltH*						
6. Insect Fragments – Other*						
7. Fly Setae						
8. Other Insect FiltH (describe)						
9. Mites*						
10. Other Arthropods						
11. Rat/Mouse Hairs (include size)						

ATTACHMENT A (continues)

12. Cat/Dog Hairs (include size)						
13. Other Striated Hairs (include size)						
14. Human Hairs (include size)						
15. Other Non-Striated Hairs (ID & size)						
16. Feather Fragments (size)						
17. Other (Describe)						
18. Other (Describe)						
19. Other (Describe)						
20. Other (Describe)						
This form should be shared with the home district and ORA/ OFFO/FFPOB @ ORA HQ FOOD FEED PROGRAM REPORTING.						

*** IDENTIFY WHEN POSSIBLE.**

**** INCLUDE COPY OF INGREDIENT STATEMENT, WHEN AVAILABLE.**

ATTACHMENT B

List of Standardized Cheeses with Phenol Levels from 21 CFR Part 133		
Cheese	Fg phenol/ g cheese	CFR Reference
Brick	20	133. 108(a)(2)
Cheddar	12	133. 113(a)(2)
Colby	12	133. 118(c)(2)
cook cheese, koch kaese	12	133. 127(a)(2)
washed curd and soaked curd	12	133. 136(a)(2)
Edam	12	133. 138(a)(2)
granular and stirred curd	12	133. 144(a)(2)
Gruyere	12	133. 149(a)(2)
Hard	12	133. 150(c)(2)
Limburger	16	133. 152(a)(2)
monterey & monterey jack	12	133. 153(a)(2)
mozzarella & scamorza	12	133. 155(a)(2)
low moisture mozzarella & scamorza	12	133. 156(a)(2)
muenster & munster	12	133. 160(a)(2)
pasteurized process	12	133. 169(a)(2)

ATTACHMENT B (continues)

Cheese	Fg phenol/ g cheese	CFR Reference
pasteurized process cheese food	12	133. 173(a)(2)
pasteurized neufchatel cheese spread with other foods	12	133. 178(a)(2)
pasteurized process cheese spread	12	133. 179(a)(2)
Provolone	12	133. 181(a)(2)
Samsae	12	133. 185(a)(2)
Semisoft	20	133. 187(c)(2)
semisoft part-skim	20	133. 188(c)(2)
Spiced	12	133. 190(a)(2)
swiss & emmentaler	12	133. 195(a)(2)

NOTE: The phenol equivalent value per gram of cheese was obtained by multiplying the value listed in the 21 CFR reference by 4.